DP Barcode: D436376 MRID No.: 49617844

DATA EVALUATION RECORD
HONEY BEE - DIETARY LC_{50}TEST
NON-GUIDELINE STUDY

1. **CHEMICAL:** Transfluthrin PC Code No.: 129140

2. **TEST MATERIAL: Transfluthrin Technical** Purity: 97.7%

3. **CITATION**

Authors:	T.L. Sloman, and J.R. Porch
Title:	Transfluthrin: An Acute Oral Toxicity Study with the Honey Bee. Final Report.
Study Completion Date:	December 18, 2015
Laboratory:	Wildlife International, Easton, Maryland, USA.
Sponsor:	Bayer CropScience, Ecotoxicology, Research Triangle Park, North Carolina, USA.
Study ID:	149P-109C
Activity ID:	EBTBN010
MRID No.:	49617844
DP Barcode:	436376

4. **REVIEWED BY:** Mary Samuel, Environmental Scientist, CDM/CSS-Dynamac JV

Signature: Marysamuel **Date:** 01/12/2017

APPROVED BY: Moncie V. Wright, Environmental Scientist, CDM/CSS-Dynamac JV

Signature: Moncie V Wright **Date:** 2/15/2017

5. **APPROVED BY:** Frank T. Farruggia, Senior Scientist, OPP/EFED/ERB1

Signature: 2017.11.21 09:13:16 -05'00' **Date:** 9/11/2017

This Data Evaluation Record may have been altered by the Environmental Fate and Effects Division subsequent to signing by CDM/CSS-Dynamac JV personnel.

6. **DISCLAIMER:** This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to honey bees via oral and contact exposure routes. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine

for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

7. STUDY PARAMETERS:

Scientific Name of Test Organism:	*Apis mellifera*
Age of Test Organism at Test Initiation:	Young adult worker honey bees
Type of Concentrations:	Actual uptake (oral)
Definitive Test Duration:	48 hours

8. CONCLUSIONS:

The honey bee, *Apis mellifera,* was exposed to **Transfluthrin Technical** for 48 hours via the dietary route. The actual intake concentrations adjusted for the % purity were 0 (negative and solvent controls), and 0.0052, 0.021, 0.062, 0.15, and 0.50 µg ai/bee.

By 48 hours, no mortalities, abnormal effects, or other sublethal effects were observed in the negative control or the 0.0052 µg ai/bee treatment group. In the solvent control, mortality was 7% at study termination. At 48 hours, mortality was 3, 3, 20, and 13% in the 0.021, 0.062, 0.15, and 0.50 µg ai/bee treatment groups, respectively. One bee was lethargic in the 0.062 µg ai/bee treatment group at 48 hours. The LC_{50} was >0.50 µg ai/bee.

This is a non-guideline study and cannot be used to satisfy guideline data requirements.

9. ADEQUACY OF THE STUDY:

A. Classification: This study **is scientifically sound** and is classified as **acceptable**

B. Rationale:

C. Repairability:

10. GUIDELINE DEVIATIONS: The study author designed the study to comply with OECD 213: OECD Guideline for the Testing of Chemicals, *Honeybees, Acute Oral Toxicity Test*, (adopted 21st September 1998); and EPPO Guideline 170, Efficacy Evaluation of Plant protection Products, Side-Effects on Honeybees (1975).

The reviewer assessed the study methods and results according to OECD Guideline 213. No deviations were noted.

11. SUBMISSION PURPOSE: Reregistration

12. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera, Megachile rotundata,* or *Nomia melanderi*)	*Apis mellifera*
Age at beginning of test:	Young adult worker honey bees (recently emerged)
Supplier:	Bayer CropScience, LP, Research Triangle Park, North Carolina, USA.
All bees from the same source?	Yes

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Stainless steel cylinders (*ca.* 9 cm diameter and 9 cm high) with perforation for ventilation and covered in wire-mesh window screening. Each end of the cylinder was covered with a disposable petri dish (*ca.* 10 cm diameter) and the bottom of the petri dish was lined with filter paper.
Lighting:	Continuous darkness, except during dosing and observations.
Temperature:	25-27°C
Relative humidity:	53-68%

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No.

Guideline Criteria	Reported Information
Reference toxicant test?	Yes; dimethoate, 99.4% purity.
Method of administration:	Bees were fed a dosed or untreated 50% w/v aqueous sucrose solution (100 µL) using a polystyrene grafting cup glued to the filter paper on the bottom of the test chamber. Approximately six hours after test initiation, the feeder cup was removed and replaced with a feeder cup containing untreated 50% w/v aqueous sucrose solution provided in an inverted glass vial (20 mL) inserted through the lid of the chamber. The amount of diet remaining was measured using a Hamilton gas-tight syringe.
Nominal doses:	0.012, 0.037, 0.11, 0.33 and 1.0 µg ai/bee
Controls: Negative control and/or diluent/solvent control	Negative control: 50% w/v sucrose solution. Solvent control: 5% acetone in 50% w/v sucrose solution.
Number of colonies per group:	10 worker bees per replicate, 3 replicates per control and test concentration (total of 30 bees)
Solvent: The following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	Acetone
Feeding:	50% (w/v) aqueous sucrose solution *ad libitum* during testing period.
Observations period:	2, 3, 24 and 48 hours

13. <u>REPORTED RESULTS</u>:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes. This study was performed in compliance with the GLP standards published by the USEPA (40 CFR Part 160, 1989); OECD Principles of GLP (1998), and Japan MAFF (1999).
Control performance:	Negative control: 0% mortality Solvent control: 6.7% mortality
Raw data included:	Yes
Signs of toxicity (if any) were described?	Yes

Mortality - Oral Test

Dosage µg ai/bee (actual intake; corrected for % purity)	No. of bees	Percent Mortality (%)			
		Hour of Study			
		2	3	24	48
Test Substance					
Negative Control	30	0	0	0	0
Solvent Control	30	0	0	7	7
0.0052	30	0	0	0	0
0.021	30	0	0	0	3
0.062	30	0	0	3	3
0.15	30	0	0	17	20
0.50	30	0	0	13	13
Toxic Standard					
0.028	30	0	0	3	7
0.043	30	0	0	0	0
0.14	30	0	0	43	50

Observations: No mortalities, abnormal effects, or other sublethal effects were observed in the negative control and in the 0.0052 µg ai/bee treatment group. In the solvent control, mortality was 7% at study termination. At 48 hours, mortality was 3, 3, 20, and 13% in the 0.021, 0.062, 0.15, and 0.50 µg ai/bee treatment groups, respectively. One bee was lethargic in the 0.062 µg ai/bee treatment group at 48 hours.

Statistical method: The Lowest Observed Adverse Effects Concentration (LOAEC) and the No Observed Adverse Effects Concentration (NOAEC) were determined by statistical analysis of the mortality data using Fisher's Exact Test in SAS Version 9.4 and by visual interpretation of the mortality data. Mortality data for the negative and solvent control groups were also compared using Fisher's Exact Test. The LC_{50} value was visually determined.

Reported Statistical Results:

LC_{50}: >0.50 µg ai/bee 95% C.I.: N/A
Probit Slope: N/A

NOAEC: 0.062 µg ai/bee LOAEC: 0.15 µg ai/bee

14. VERIFICATION OF STATISTICAL RESULTS:

Statistical method: The mortality data and nominal concentrations adjusted for actual dietary intake and the % purity of the test material were entered into the program CETIS, (Version 1.8.7.12) with backend settings implemented by EFED on 10/20/15. The LC_{50} value was visually determined by the reviewer due to a lack of toxicity in this study culminating in effects ≥50%.

Results - Oral Test:
LC_{50}: >0.50 µg ai/bee 95% C.I.: N/A
Probit Slope: N/A

15. REVIEWER'S COMMENTS:

The reviewer's and the study author's results were in complete agreement. The reviewer's results were based on the actual intake of the test concentrations adjusted for % purity of the technical material. The reviewer's results are presented in the Conclusions section of this DER.

The in-life phase of the oral toxicity test was conducted from September 02, 2015 to September 04, 2015.

16. REFERENCES:

Sloman, T. and Porch, J. 2015. Transfluthrin: an acute contact toxicity study with the honey bee. Wildlife International. Study ID: 149P-110. Bayer Activity ID: EBTBN011.

European and Mediterranean Plant Protection Organization. 2000. *Efficacy Evaluation of Plant Protection Products, Side-Effects on Honeybees*. EPPO Bulletin, PP 1/170(3), 95-99.

Atkins, E. L., E. A. Greywood, and R. L. Macdonald. 1975. Toxicity of pesticides and other agricultural chemicals to honey bees: Laboratory studies. *Univ. of Calif. Div. of Agric. Sci. Leaflet 2287*. 38 pp.

SAS Institute, Inc. 2002-2012. SAS Proprietary Software Version 9.4, Cary, NC, SAS Institute, Inc.

Stephan, C.E. 1978. U.S. EPA, Environmental Research Laboratory, Duluth Minnesota. Personal Communication.

Finney, D.J. 1971. *Statistical Methods in Biological Assay.* Second edition. Griffin Press, London.

Thompson, W.R. 1947. *Bacteriological Reviews.* Vol II, No. 2: 115-145.

Stephan, C.E. 1977. Methods for Calculating an LC50. Pages 65-84 In *Aquatic Toxicology and Hazard Evaluations*, American Society for Testing and Materials. Pub. No. STP 634. Philadelphia, PA.

OECD TG213 Honey bee Adult Acute Oral Toxicity — **Wildlife International**

Batch ID:	07-2383-4499	**Test Type:**	OECD 213 Honeybee Acute Oral	**Analyst:**	
Start Date:	02 Sep-15	**Protocol:**	OECD 213: Honey Bee Oral	**Diluent:**	Aqueous Sucrose
Ending Date:	04 Sep-15	**Species:**	Apis mellifera	**Brine:**	
Duration:	48h	**Source:**	Bayer CropScience AG	**Age:**	

Sample ID:	13-7885-9378	**Code:**	49617844	**Client:**	CDM Smith - M. Wright
Sample Date:	02 Sep-15	**Material:**	Transfluthrin	**Project:**	
Receive Date:	04 Sep-15	**Source:**	Bayer CropScience		
Sample Age:	NA	**Station:**			

Batch Note: 129140 49617844
Sample Note: 129140 49617844

24h Mortality Rate Summary

C-µg ai/bee	Control Type	Count	Mean	95% LCL	95% UCL	Min	Max	Std Err	Std Dev	CV%	%Effect
0	Solvent Blank	3	0.0667	0	0.354	0	0.2	0.0667	0.115	173.0%	0.0%
0	Negative Control	3	0	0	0	0	0	0	0		-7.14%
0.0052		3	0	0	0	0	0	0	0		-7.14%
0.021		3	0	0	0	0	0	0	0		-7.14%
0.062		3	0.0333	0	0.177	0	0.1	0.0333	0.0577	173.0%	-3.57%
0.15		3	0.167	0	0.684	0	0.4	0.12	0.208	125.0%	10.7%
0.5		3	0.133	0	0.42	0	0.2	0.0667	0.115	86.6%	7.14%

48h Mortality Rate Summary

C-µg ai/bee	Control Type	Count	Mean	95% LCL	95% UCL	Min	Max	Std Err	Std Dev	CV%	%Effect
0	Solvent Blank	3	0.0667	0	0.354	0	0.2	0.0667	0.115	173.0%	0.0%
0	Negative Control	3	0	0	0	0	0	0	0		-7.14%
0.0052		3	0	0	0	0	0	0	0		-7.14%
0.021		3	0.0333	0	0.177	0	0.1	0.0333	0.0577	173.0%	-3.57%
0.062		3	0.0333	0	0.177	0	0.1	0.0333	0.0577	173.0%	-3.57%
0.15		3	0.2	0	0.857	0	0.5	0.153	0.265	132.0%	14.3%
0.5		3	0.133	0	0.42	0	0.2	0.0667	0.115	86.6%	7.14%

24h Mortality Rate Detail

C-µg ai/bee	Control Type	Rep 1	Rep 2	Rep 3
0	Solvent Blank	0	0	0.2
0	Negative Control	0	0	0
0.0052		0	0	0
0.021		0	0	0
0.062		0	0	0.1
0.15		0	0.1	0.4
0.5		0.2	0.2	0

48h Mortality Rate Detail

C-µg ai/bee	Control Type	Rep 1	Rep 2	Rep 3
0	Solvent Blank	0	0	0.2
0	Negative Control	0	0	0
0.0052		0	0	0
0.021		0	0	0.1
0.062		0	0	0.1
0.15		0	0.1	0.5
0.5		0.2	0.2	0